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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,424	05/30/2001	Anton-Lewis Usala	35626/234826	7082

826 7590 01/25/2005

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EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,424

Applicant(s)

USALA, ANTON-LEWIS

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 14, 15, 34, 40, 44 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 16-21, 25-33, 35-39, and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/12/01 & 4/12/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response of December 12, 2004 is acknowledged. Due to the citation of new prior art the present action is made NON-FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 13, 16-21, 25-28, 30-33, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz et al. (US 6238888 B1) in view of Obi-Tabot (US6046160) and Sojka et al. (US 6,491,953).

Gentz et al. is discussed in the previous action. Gentz et al. teach the use of formulations to stimulate hair follicle production (col. 21, lines 27-28) comprising collagen (col. 9, lines 34-45) and dextran (col. 9, line 29), glutamic acid (col. 13, line 5), cysteine (col. 4, lines 55), and EDTA (col. 13, line 8). Although Gentz et al. teach the use of collagen, Gentz et al. does not expressly teach the use of Applicant's elected gelatin component denatured collagen (see Applicant's claims 3 and 30). Additionally, although Gentz et al. teach a liquid hair growth composition that solidifies at about 37 degrees Celcius (col. 8, lines 54-60), Gentz et al. does not expressly teach the use of a matrix that solidifies at below about 33 degrees Celcius.

Obi-Tabot is discussed in the previous action. Obi-Tabot generally teaches that collagen in skin treatments can be preferably denatured which can be "solubilized for easy application as

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a gelatin-like solution. When cooled, the collagen is partially renatured, resulting in a gel formation with excellent tensile strength”, that can be easily injected (col. 13, lines 17-30).

Specifically, Obi Tabot teach the use of denatured collagen in similar compositions.

Sojka et al. teach the use of a hair growth promoting composition (col. 7, lines 39 and 43) with the addition of for hair growth in liquid form that solidifies at below about 33 degrees Celcius (36-40).

It also would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the denatured collagen of Obi Tabot in the composition of Gentz et al., because Obi Tabot teach the advantageous use of denatured collagen and the use of collagen in a denatured form would be merely routine optimization of one of ordinary skill in the art. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Additionally, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a hair growth promoting composition in liquid form that becomes solid at about below 33 degrees Celcius in Gentz et al., because Sojka et al.’s advantageous use of a hair growth promoting composition that solidifies below about 33 degrees Celcius.

Claims 1-10, 13, 16-21, 25-33, 35-39, and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gentz et al. (US 6238888) in view of Obi-Tabot (US6046160) and Sojka et al. (US 6,491,953) and further in view of Naughton et al. (US 6372494).

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Gentz et al., Obi-Tabot, and Sojka et al. are all discussed above. Gentz et al. does not expressly teach the injection of the composition (Applicant's claims 29 and 43).

Gentz et al. does not expressly teach that the composition may be injected.

Additionally, although Gentz et al. generally describe the use of the present invention's compounds in varying amounts, the reference does not expressly teach all the various mM of collagen, Daltons of dextran, or mM of glutamic acid, or μ M of cysteine (Applicant's claims 5-6, 8-9, 13, 18-21, 27, and 37-39).

Naughton et al. is discussed in the previous actions. Naughton et al. teach a method of stimulating hair growth (col. 1, lines 14-15) using a hydrogel matrix (claim 9) composition comprising gelatin (collagen) and a long chain carbohydrate (dextran)(col. 11, lines 66-67); as well as amino acids such as glutamic acid (col. 9, lines 4-12); and EDTA (col. 7, line 8); that may be injected (col. 26, line 13). [Note: Although Naughton et al. teach any amino acid generally, cysteine was not expressly claimed]. Specifically, Naughton et al. teach the *injection* of similar compositions.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to inject the hair follicle stimulating formulation of Gentz et al., because Naughton et al. teach the advantageous injection of a hair growth composition with like compounds.

It also would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use various mM of collagen, Daltons of dextran, or mM of glutamic acid, or μ M of cysteine in the composition for hair follicle stimulation of Gentz et al. because the additional of different amounts of such compounds for desired effects is well within the preview

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of one of skill in the art and a matter of routine optimization. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Applicant's Arguments

Applicant's arguments with respect to the art rejections have been carefully considered but are not deemed persuasive of error in the rejection. Applicant has argued that Gentz et al. does not teach that the composition can be in liquid or solid form at certain temperature (i.e. below 33 degrees Celcius). This is not found persuasive, because, although Gentz et al. generally only teaches a liquid to solid at about 37 degrees Celcius, the art teaches through Sojka et al. that it was known in the art to add release retardants with hair growth promoters to impute a solid state below about 33 degrees Celcius. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a hair growth promoting composition in liquid form that becomes solid at about below 33 degrees Celcius in Gentz et al., because Sojka et al.'s advantageous use of a hair growth promoting composition that solidifies below about 33 degrees Celcius.

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Applicant has argued that Naughton et al. does not teach or suggest the present invention because the claimed invention of Naughton et al. is directed to a cell culture medium. This is not found persuasive, because Naughton et al. is cited to show that *similar formulations may be injected* (Applicant's limitation in i.e. claim 43). Naughton et al. nevertheless teaches the advantageous use of a composition (i.e. with EDTA, etc.) which may be injected intradermally. Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to inject the hair follicle stimulating formulation of Gentz et al., because Naughton et al. teach the advantageous injection of a hair growth composition with like compounds.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 01/20/2005



CHRISTOPHER R. TATE
PRIMARY EXAMINER